



(Re.177-10/98 Pub.605)

FORM 6-4

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Practitioner's Docket No. 1581/128 PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Kanakaris, et al.

Application No: 09 /762,602

Group No.: 1617

Filed: March 21, 2001

Examiner: Hui

For: USE OF MISOPROSTOL OR/AND MISOPROSTOL ACID FOR PREPARING DRUG IN
ORDER TO CURE SEXUAL DYSFUNCTION IN WOMEN

Commissioner for Patents
Washington, D.C. 20231

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
BEFORE MAILING DATE OF EITHER A FINAL ACTION
OR NOTICE OF ALLOWANCE (37 C.F.R. § 1.97(c))**

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under § 1.113 or (2) a notice of allowance under § 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of section 1.97 or the fee set forth in § 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. § 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))

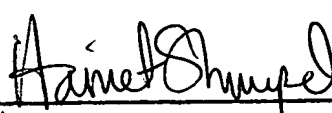
I hereby certify that this correspondence is, on the date shown below, being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the
Commissioner for Patents,
Washington, D.C. 20231.

FACSIMILE

☐ transmitted by facsimile to the
Patent and Trademark Office.


Signature

Harriet M. Strimpel, D.Phil.

(type or print name of person certifying)

Date: October, 17, 2001

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance [6-4]—page 1 of 3)

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01-PC-486

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in § 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,whichever occurs first.

STATEMENT OR FEE

2. Accompanying this transmittal is

(check either A or B below)

- A. ☐ a statement as specified in 37 C.F.R. § 1.97(e).

OR

- B. ☒ the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c). (\$240.00).

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. § 1.17(p) for submission of an information disclosure statement under § 1.97(c) \$180.00

Fee due \$ 180.00

METHOD OF PAYMENT OF FEE

4.

- ☒ Attached is a check in the amount of \$ 180.00.
- ☐ Charge Account No. _____ in the amount of \$ _____.

A duplicate of this request is attached.

If any additional fees are due, please charge Account 19-4972.

(Transmittal of Information Disclosure Statement before Mailing Date of Either a Final Action Or Notice of Allowance [6-4]—page 2 of 3)

Reg. No. 337,008

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Customer No.: 00-21-1



SIGNATURE OF PRACTITIONER

Harriet M. Strimpel, D.Phil.

(type or print name of practitioner)

Bromberg & Sunstein, LLP

125 Summer Street, Boston, MA 02110

P.O. Address

Practitioner's Docket No. 1581/128

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of _____

Inventor(s)

for _____

Title of invention

OR

In re application of: Kanakaris et al.

Application No.: 09/762,602

Group Art Unit: 1617

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For: USE OF MISOPROSTOL OR/AND MISOPROSTOL ACID FOR PREPARING DRUG IN
ORDER TO CURE SEXUAL DYSFUNCTION IN WOMEN**Commissioner for Patents
Washington, D.C. 20231****INFORMATION DISCLOSURE STATEMENT****CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10****(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

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- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents,
Washington, D.C. 20231

37 C.F.R. § 1.8(a)**37 C.F.R. § 1.10***

- ☒ with sufficient postage as first class mail.

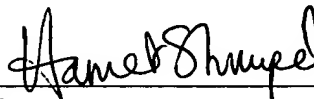
☐ as "Express Mail Post Office to Addressee"

Mailing Label No. _____ **(mandatory)****TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: October 17, 2001

Signature



Harriet M. Strimpel, D. Phil.

(type or print name of person certifying)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13 -25 at 17.

WARNING: "No information disclosure statement maybe filed in a provisional application." 37 C.F.R. § 1.51(d).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary Statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:

"A legible copy of.:

- (i) Each U.S. patent application publication and U.S. and foreign patent;*
- (ii) Each publication or that portion which caused it to be listed,*
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type or print name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

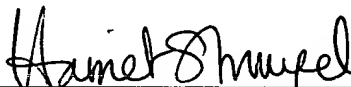
(type or print name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
- ☒ in the practitioner's file.

Reg. No.: 37,008



SIGNATURE OF PRACTITIONER

Tel. No.: 617/443-9292

Harriet M. Strimpel, D. Phil.
(type or print name of person certifying)

Customer No.: 00-2101

Bromberg & Sunstein LLP
125 Summer Street, Boston, MA 02110